REMARKS

Claims 1 and 4 are currently amended. Claims 6-8 and 14 are hereby cancelled without prejudice to or disclaimer of the underlying subject matter. As such, by the present Amendment, Claims 1, 2, 4 and 9-12 are pending. No new matter is added by way of these amendments.

I. Claim Rejections under 35 U.S.C. § 101

The Examiner rejected claims 1-2, 4, 6-12 and 14 under 35 U.S.C. § 101, because the claimed invention allegedly "is not supported by either a specific or substantial asserted utility or a well established utility." Office Action at page 2. Applicants respectfully disagree with this allegation.

In *In re Fisher*, the Federal Circuit reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (citing *Brenner v. Manson*, 383 U.S. at 534-35, 1966) (emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an

application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public.*" *Id.* (emphasis in original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

The Examiner alleged that the "claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any EST." Office Action at page 3. The Examiner further alleged that ". . . the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any prior art of record discloses or suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the compounds." Office Action at page 5. Applicants respectfully disagree.

Applicants submit that the BLASTX analysis submitted in the response mailed October 27, 2008 demonstrates that SEQ ID NO: 11 has significant correlation to SEQ ID NO: 13 of U.S. Patent 5,723,595. *See e.g.,* Response mailed October 27, 2008 at page 5. The BLASTX results establish a reasonable correlation of SEQ ID NO: 11 to an acyl ACP desaturase and as such, Applicants have provided a specific, substantial, and credible utility for SEQ ID NO: 11. Moreover, because this sequence was available to the skilled artisan at the time of filing, this utility was a well-established utility.

Despite the evidence demonstrating a significant and reasonable correlation of SEQ ID NO: 11 to acyl ACP desaturase, the Examiner maintained the utility rejection, arguing that Applicants previously "asserted that based on BLAST[N] analysis, SEQ ID NO: 11 correlated to storage proteins in plants . . . [having] 95 percent identity over 92 percent of the length of a storage protein sequence obtained from *Triticum aestivum*."[1] Office Action at page 7, (internal quotes omitted). The Examiner further asserted that "as evidenced by the citations provided by applicants with regard to storage proteins vs ACP desaturases, these proteins are structurally and functionally different." Office Action at page 7.

However, Applicants respectfully submit that "BLASTN was designed for speed, not maximum sensitivity...." Specification at page 16, lines 10-12. Further, "[g]iven a coding nucleotide sequence and the protein it encodes, it is often preferable to use the protein as the query sequence to search a database because of the greatly increased sensitivity to detect more subtle relationships." Specification at page 16, lines 20-23 (emphasis added). Here, Applicants have provided evidence by protein sequence comparison that SEQ ID NO: 11 has a strong correlation to acyl ACP desaturase.

Applicants respectfully remind the Examiner that the utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). In light of the evidence provided by Applicants, "[t]he examiner has the initial burden of challenging an asserted utility. Only after the examiner has provided evidence showing

[1] Applicants submit that the prior BLASTN analysis identified a sequence of 95% identity to nucleotide sequence BJ310230 published as part of the analysis published by Kawaura et al. submitted in the IDS filed October 26, 2008 as item U.

that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility." *In re Swartz,* 232 F.3d 862, 863, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981))(emphasis added).

The Examiner asserted that

> "[t]he fact that the responses have asserted "correlations" to structurally and functionally different proteins using BLAST analysis, and the specification is entirely silent as to whether SEQ ID NO: 11 encodes a protein, or expression analysis or a function for a protein encoded by SEQ ID NO: 11, whether it functions as a storage protein or ACP desaturase illustrates that no immediate benefit has been disclosed by the specification at the time the invention was filed nor was the function of SEQ ID NO: 11 well established in the art at the time the invention was filed."

Office Action at page 8.

However, Applicants respectfully remind the Examiner that "an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983). That the sequence may have additional correlations and additional utilities is not evidence that one of skill in the art would reasonably doubt the asserted utility that SEQ ID NO: 11 is an acyl ACP desaturase.

In fact, one of skill in the art would recognize that the high degree of identity and homology observed between SEQ ID NO: 11 and other acyl ACP desaturase proteins provides for the assignment of enzyme function by sequence comparison. As further support, Applicants submit an additional BLASTX alignment showing a significant correlation to another acyl ACP desaturase known as of the priority date of the instant application:

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>gb|AAB65144.1| stearoyl-ACP desaturase [Helianthus annuus]
Length=396
Score = 163 bits (413), Expect = 4e-39
Identities = 84/130 (64%), Positives = 99/130 (76%), Gaps = 6/130 (4%)
Frame = +2
Query 2   AYTKVAAKVFELDPDGMVQALAAVLRDKITMPGQLMTDGRDADLFEHFSAVAQRTGVYTA 181
          AYTK+A K+FE+DPDG V A A ++R KI+MP LM DGRD DLF+HFSAVAQR GVYTA
Sbjct 268 AYTKIAEKLFEIDPDGTVLAFADMMRKKISMPAHLMYDGRDDDLFDHFSAVAQRLGVYTA 327

Query 182 RDYGDMVEHFVRRWKVADLGGGQLSGEGRRAQEYVCGLPRKIRRVEELAHDRVIKAAKEP 361
           +DY D++E V RWKVADL G LSGEGR+AQ+YVCGLP +IRR+EE A R AKE
Sbjct 328 KDYADILEFLVGRWKVADLTG--LSGEGRKAQDYVCGLPSRIRRLEERAAAR----AKEG 381

Query 362 EFARFSWVFD 391
               FSW+FD
Sbjct 382 PSIPFSWIFD 391
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Here, SEQ ID NO: 11 is shown to match Genbank ID AAB65144 stearoyl-ACP desaturase from *Helianthus annuus* with 64% identity and 76% homology. It was known at the time of filing that a sequence identity of 50%[2] or even 40%[3] may be sufficient to assign a functional classification to a new sequence. Indeed, Applicants respectfully submit that there are many proteins that are encoded by nucleic acid sequences which are highly conserved across a number of species, and that one of ordinary skill in the art would recognize that SEQ ID NO: 11 is highly conserved to a *Helianthus annuus* sequence that encodes stearoyl [acyl] ACP desaturase and is itself an acyl ACP desaturase. As such, one of skill in the art would have been aware that SEQ ID NO: 11 has specific, substantial, or credible utility and can be used in a manner that provides immediate benefit to the public.

As the Examiner is aware, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93

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[2] Cyrus A. Wilson *et al.*, *Assessing annotation transfer for genomics: quantifying the relations between protein sequence, structure and function through traditional and probabilistic scores*, 297 J. Mol. Biol. 233, 233-249 (2000). Available online June 6, 2000.

[3] Annabelle E. Todd *et al. Evolution of protein function, from a structural perspective*, 3 Current Opinion in Chemical Biology, 548, 548-556 (1999).

F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. The BLASTX analysis showing a 64% percent identity and 76% homology over the length of SEQ ID NO: 11 is a reasonable correlation supporting the specific, substantial and credible utilities asserted for SEQ ID NO: 11.

Accordingly, based on the foregoing, Applicants respectfully submit that they have satisfied the utility test set forth in *In re Fisher*. As of Applicants' effective filing date of June 14, 1999, one of skill in the art would have been aware that SEQ ID NO: 11 was correlated (*e.g.*, E-value = 4e-39) to an acyl ACP desaturase. Indeed, SEQ ID NO: 11 has a reasonable correlation with acyl ACP desaturases from multiple organisms. As such, in accordance with *Fisher*, as of the effective filing date, the claimed invention had utility as it provided well-defined and particular benefits to the public. Based on the foregoing, Applicants respectfully request that the Examiner withdraw the rejection of Claims 1, 2, 4 and 9-12 under 35 U.S.C. § 101.

II. Claim Rejections under 35 U.S.C. § 112, first paragraph (Enablement):

The Examiner rejected Claims 1-2, 4, 6-12 and 14 as not being enabled because the claimed invention is allegedly "not supported by either a specific, substantial and credible asserted utility or a well established utility" and "one skilled in the art clearly would not know how to use the claimed invention." Office Action at page 6. For at least the reasons presented above, Applicants have established specific, substantial, credible and well-established utilities

for SEQ ID NO: 11, and therefore one skilled in the art would know how to make and use the claimed invention. On this basis, Applicants request withdrawal of the rejection of Claims 1, 2, 4 and 9-12 under 35 U.S.C. § 112, first paragraph.

III. Claim Rejections under 35 U.S.C. § 112, first paragraph (Written Description):

The Examiner rejected claims 2, 8 and 14 under 35 U.S.C. § 112, first paragraph, as allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 8-9. Applicants thank the Examiner for the acknowledging that SEQ ID NO: 11 "meets the written description requirement of 35 USC 112, first paragraph." Office Action at page 9.

In rejecting Claims 2, 8 and 14, the Examiner alleged

> SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. . . . The specification does not teach the function of the larger protein encoded by SEQ ID NO: 11, and provides no description of the remainder of the coding sequence of which SEQ ID NO: 11 appears to be a part of. It is not clear what peptide is encoded by SEQ ID NO: 11, as the specification does not teach, for example, if nucleotide position #1 of SEQ ID NO: 11 is the first nucleotide in a codon, or the second or third.

Office Action at page 9.

However, the purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in

the sense of 35 U.S.C. § 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981). Thus, in order for Applicants to describe all of the molecules encompassed by the claims, it is not required that each and every aspect of those nucleic acid molecules be disclosed. *In re Alton*, 76 F.3d at 1175 (if a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met).

In the present case, SEQ ID NO: 11 can encode, based on 6 different reading frames, a fully described set of wheat proteins or fragment of wheat proteins. One of skill in the art can readily do a translation of the nucleotide sequence to unambiguously identify all potential proteins. Further, as shown above, BLASTX analysis identifies reading frame +2 as strongly correlated with an acyl ACP desaturase. As the M.P.E.P. clearly states, "A patent specification need not teach, and preferably omits, what is well known in the art." M.P.E.P. at § 2182 citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). In light of the disclosure of the specification, the reading frame of the claimed nucleic acid molecules, including nucleic acid molecules encoding a wheat protein or fragment thereof, would be readily apparent to one of skill in the art.

The Examiner maintained the rejection of Claim 2 arguing that "[w]hile the sequence of SEQ ID NO: 11 is common to the genus claimed in claim 2, claim 2 is broadly drawn to sequences comprising SEQ ID NO: 11 and not all sequences comprising SEQ ID NO: 11 necessarily encode a wheat protein." Office Action at page 13. Applicants respectfully disagree with the Examiner's argument. Claim 2 recites "[t]he substantially purified nucleic acid molecule of claim 1, wherein said nucleic acid molecule encodes a wheat protein or fragment of a wheat protein." As such, the fact that "sequences comprising SEQ ID NO: 11 do not necessarily encode a wheat protein" is irrelevant. What is relevant is that Claim 2 includes sequences of Claim 1 that do "encode a wheat protein or fragment of a wheat protein." See Claim 2.

The Examiner also alleged that "Claim 8 is drawn to a nucleic acid molecule which comprises at least portion of SEQ ID NO: 11 and a region comprising at least one single nucleotide polymorphism (SNP). . . . Each member of the claimed genus does not contain the same structural feature" Office Action at page 10. To facilitate prosecution and without prejudice or disclaimer to the underlying subject matter, Applicants have cancelled claim 8.

The Examiner also alleged that "[n]ewly added claim 14 recites 'fragment of a protein having greater than 30 amino acids'". Office Action at page 12. According to the Examiner, "[t]he specification has been thoroughly reviewed but does not provide support for such and thus the amendment appears to have introduced new matter into the claimed invention." *Id.* To facilitate prosecution and without prejudice to or disclaimer of the underlying subject matter, Applicants have cancelled claim 14.

In support of the rejections under 35 U.S.C. § 112, the Examiner cites to Skolnick (Jeffery Skolnick and Jacquelyn S. Fetrow, *From genes to protein structure and function: novel applications of computational approaches in the genomic era*, 18 TIBTECH 34, 34-39 (2000), hereinafter "Skolnick") stating that "the state of the art teaches that sequence comparison alone is not a reliable indicator of a protein's function. . . . [and] a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional." Office Action at page 11.

To the extent that the Examiner relies on Skolnick as a basis for rejecting the claims under 35 U.S.C. § 112 , Applicants respectfully submit that the Examiner misapplies the teachings of Skolnick and further, that Skolnick's conclusions are contradicted by both pre- and post-filing references. *See e.g.,* Office Action at page 11. At the time of filing, as discussed above, "precise function appears to be conserved down to approximately 40% sequence identity, whereas broad functional class is conserved to approximately 25 %." *See* Wilson at abstract. Indeed, even Skolnick and colleagues conclude that "[their] results suggest that for functional annotation, 40% sequence identity can still be used as a confident threshold to transfer the first three digits of an EC number. However, to transfer all four digits of an EC number, above 60% sequence identity is needed to have above 90% accuracy." W. Tian and J. Skolnick, *How Well is Enzyme Function Conserved as Function of Pairwise Sequence Identity?* 333. J. Mol. Biol. 863, 865 (2003).

The Federal Circuit has elucidated a test for written description whereby a genus of nucleic acids can be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli*

Lilly and Co., 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). Applicants have satisfied that test for written description. The Examiner acknowledges that Appellants have disclosed the common structural feature of SEQ ID NO: 11. Office Action at page 9. Thus, if a particular nucleic acid molecule contains the nucleotide sequence of SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 11. Moreover, related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable – they either contain the nucleic acid sequence of SEQ ID NO: 11 or they do not. The fact that the claimed nucleic acid molecules may comprise additional sequences is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. *See, for example,* Specification at page 20, lines 14-23 (describing transformed plants comprising nucleic acid constructs), at page 64, line 24 to page 71, line 4 (describing various gene constructs including for example promoters, transit peptides and selectable markers).

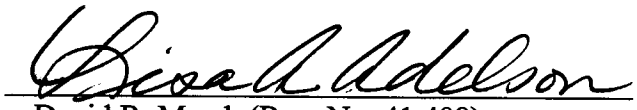
Therefore, for at least these reasons, Applicants respectfully submit that they have provided sufficient description to reasonably convey to one skilled in the relevant art that at the time the application was filed, the Applicants had possession of the claimed invention. Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, written description, is improper and its withdrawal is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5325 if any additional information is necessary for allowance.

Respectfully submitted,

Date: June 17, 2009



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